

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BOARD OF APPEALS AND INTERFERENCES**

In re Application of: Zecchino et al.

| | | | |
|-------------|--------------------------------------|-----------------|------------|
| Serial No.: | 09/995,358 | Group Art Unit: | 1618 |
| Filed: | November 26, 2001 | Examiner: | Fubara, B. |
| For: | GELLED AQUEOUS COSMETIC COMPOSITIONS | | |

APPELLANT'S BRIEF PURSUANT TO 37 CFR 41.31

Commissioner For Patents
Attention: Board of Patent Appeals and Interferences
Alexandria, Virginia 22313-1450

Sir:

Appellants hereby appeal to the Board of Patent Appeals and Interferences from the final rejection of claims 1-10, 12-16 and 18-26 in the present application in the decision of November 16, 2007.

REAL PARTY IN INTEREST

The name of the real party in interest in this appeal is Color Access, Inc., the assignee of the application.

RELATED APPEALS AND INTERFERENCES

There are no other appeals or interferences relating to the instant application that would directly affect, be directly affected by, or have a bearing of any kind on the Board's decision in this appeal that are known to Appellants.

STATUS OF THE CLAIMS

Claims 1-10, 12-16 and 18-21 remain pending and finally rejected in this application. The appealed claims are claims 1-10, 12-16 and 18-21, as presented in the Appellants' Preliminary Amendment submitted together with an RCE on November 28, 2006. The submission of November 28, 2006 was considered and entered by the Examiner, as noted in the Office Action Summary of March 26, 2007. The appealed claims are again presented herewith in the Claims Appendix.

STATUS OF AMENDMENTS

There has been no amendment of the claims following the final rejection of November 16, 2007.

SUMMARY OF CLAIMED SUBJECT MATTER

The invention of independent claim 1 is a cosmetic or pharmaceutical composition comprising an oil-containing biliquid foam dispersed in a salt-containing aqueous phase, the aqueous phase comprising a polymeric sulfonic acid gellant and having a pH of less than 7, the salt contained in the aqueous phase being present in the composition in an amount in the range

of from about 1 to about 10 percent, the gellant being present in the composition in an amount in the range of from about 0.01 to about 10 percent, and the composition comprising less than about 1 percent surfactant, wherein said weights are by weight of the total composition (see page 2, lines 12-14; page 3, lines 4 and 7; and claim 11 as initially filed).

The invention of independent claim 12 is a cosmetic or pharmaceutical composition comprising a silicone-oil containing biliquid foam dispersed in a salt-containing aqueous phase, the aqueous phase having a pH of less than 7 and comprising an ammonium poly(acryldimethyltauramide-co-vinylformamide) gellant; the salt contained in the aqueous phase being present in the composition in an amount in the range of from about 1 to about 10 percent, the gellant being present in the composition in an amount in the range of from about 0.01 to about 10 percent, and the composition comprising less than about 1 percent surfactant, wherein said weights are by weight of the total composition (see page 2, lines 12-14, 22; page 3, lines 4 and 7; and claim 11 as initially filed).

The invention of independent claim 19 is a method of thickening a composition comprising biliquid foam dispersed in a salt-containing aqueous phase having a pH less than 7, comprising gelling the aqueous phase with a polymeric sulfonic acid gellant; the salt contained in the aqueous phase being present in the composition in an amount in the range of from about 1 to about 10 percent, the gellant being present in the composition in an amount in the range of from about 0.01 to about 10 percent, and the composition comprising less than about 1 percent surfactant, wherein said weights are by weight of the total composition (see page 2, lines 12-14; page 3, lines 4 and 7; and claim 11 as initially filed).

GROUND OF REJECTION TO BE REVIEWED ON APPEAL

The remaining issue is: whether claims 1-10; 12-16, 18; and 19-21 are unpatentable over WO 97/32559 to Wheeler (hereinafter referred to as "the WO'559 reference"), in view of the Clariant brochure on Aristoflex® AVC (hereinafter referred to as "the Clariant reference"), under 35 USC §103(a). Specifically, the question is whether one of ordinary skill in the art, at the time the invention was made, would have had a reasonable expectation that substituting the polymeric sulfonic acid gellant taught in the Clariant reference for the conventional gellants described in the WO'559 reference would have resulted in the claimed composition which is a cosmetic or pharmaceutical composition comprising an oil-containing biliquid foam dispersed in a salt-containing aqueous phase, the aqueous phase comprising a polymeric sulfonic acid gellant and having a pH of less than 7, the salt contained in the aqueous phase being present in

the composition in an amount in the range of from about 1 to about 10 percent, the gellant being present in the composition in an amount in the range of from about 0.01 to about 10 percent, and the composition comprising less than about 1 percent surfactant.

ARGUMENT

I. Rejections under 35 USC §103(a)

Claims 1-10, 12-16, 18 and 19-21

For purposes of patentability, claims 1-10; 12-16, 18; and 19-21, drawn to the outstanding issue of the present Appeal, are grouped together. Specifically, the claims are grouped together as they apply to the rejections based on 35 U.S.C. §103(a). The outstanding issue is whether claims 1-10; 12-16, 18; and 19-21 are obvious from the WO'559 reference in view of the Clariant reference. More specifically, the question is whether one of ordinary skill in the art would have had a reasonable expectation that, modifying the stable dispersion of the WO'559, comprising an oil-based biliquid foam dispersed in an aqueous gel, by substituting the polymeric sulfonic acid gellant taught in the Clariant reference for the conventional gellants described in the WO'559, would have resulted in a stable, gelled aqueous formulation, using no more than 1% surfactant in the total formulation, where the formulation had a pH less than 7 and a significant salt concentration.

The problem addressed and solved by the present invention is how to formulate a stable and aesthetically appealing (e.g. clear and creamy) water-based gel which is cooling, gentle and non-greasy, when applied to the skin, while achieving maximum efficacy of incorporated actives, in particular, actives present as electrolytes, e.g., salts, which are known to disrupt gel structure and therefore seriously interfere with the maintenance of a stable, clear gel product. The present invention provides a product which solves the problem posed, yet not solved, by the prior art. The present invention is directed to a composition comprising an oil-containing (preferably, silicone containing) biliquid foam dispersed in a salt-containing aqueous phase, the aqueous phase comprising a polymeric sulfonic acid gellant, preferably an ammonium poly(acryldimethyltauramide-co-vinylformamide) gellant, and having a pH of less than 7, the salt contained in the aqueous phase being present in the composition in an amount in the range of from about 1 to about 10 percent, the gellant being present in the composition in an amount in the range of from about 0.01 to about 10 percent, and the composition comprising less than about 1 percent surfactant, wherein said weights are by weight of the total composition. The present invention further relates to a method of thickening a composition comprising a biliquid foam dispersed in a salt-containing aqueous phase having a pH less than 7, comprising gelling the aqueous phase with a polymeric sulfonic acid gellant; the salt contained in the aqueous phase being present in the composition in an amount in the range of from about 1 to about 10 percent,

the gellant being present in the composition in an amount in the range of from about 0.01 to about 10 percent, and the composition comprising less than about 1 percent surfactant, wherein said weights are by weight of the total composition.

Each of the cited references or combination of references fails to teach or suggest the invention as claimed.

The WO'559 reference

The Examiner's obviousness rejection is based on the WO'559 reference for teaching an oil-based biliquid foam and dispersions of the biliquid foam in an aqueous gel which are suitable for use in the cosmetics and pharmaceutical industries. The biliquid foam *per se* is a dispersion of oil droplets in an aqueous base using a small amount of surfactant. The biliquid foam further may be incorporated into an aqueous phase having a low pH and comprising a gelling agent. The reference fails to teach or suggest the Appellant's invention, including the use of the polymeric sulfonic acid gellant or the surprising and unexpected advantages of using this particular gellant in a biliquid foam-containing aqueous gel composition, since it does not disclose or suggest a composition comprising an oil-containing biliquid foam dispersed in a salt-containing aqueous phase, the aqueous phase comprising a polymeric sulfonic acid gellant and having a pH of less than 7, the salt contained in the aqueous phase being present in the composition in an amount in the range of from about 1 to about 10 percent, the gellant being present in the composition in an amount in the range of from about 0.01 to about 10 percent, and the composition comprising less than about 1 percent surfactant.

It is the Examiner's position that the WO'559 reference discloses the Appellants' invention except for the polymeric sulfonic acid gellant. The Examiner relies on the Clariant reference, for the teaching that a polymeric sulfonic acid gellant may be substituted for the gellants described in WO'559 reference, in an attempt to establish *prima facie* obviousness of the present invention.

The Clariant reference

The Clariant brochure describes the properties of a particular polymeric sulfonic acid gellant, Aristoflex® AVC, and examples of oil-in-water emulsions incorporating the gellant. The reference discloses that Aristoflex® AVC is known in the art for use as a gellant and thickener of an aqueous phase of an oil-in-water emulsion, and that the gellant may be used under low pH conditions. However, this reference too fails to teach or suggest the Appellant's invention and its surprising benefits, since it does not disclose or suggest a composition comprising an oil-

containing biliquid foam dispersed in a salt-containing aqueous phase, the aqueous phase comprising a polymeric sulfonic acid gellant and having a pH of less than 7, the salt contained in the aqueous phase being present in the composition in an amount in the range of from about 1 to about 10 percent, the gellant being present in the composition in an amount in the range of from about 0.01 to about 10 percent, and the composition comprising less than about 1 percent surfactant.

Combined teachings of the references

The combined teachings of the WO'559 and Clariant references fail to render the present invention obvious because, although one of ordinary skill in the art might have attempted a simple substitution of one known gellant for another, expecting to obtain predictable results (i.e. gelling of the aqueous phase of a low pH biliquid-containing dispersion), the person of ordinary skill in the art could not have predicted that the polymeric sulfonic acid gellant could be used to stably gel the aqueous phase in a biliquid containing aqueous gel composition, where the composition had a pH of less than 7 and a significant salt presence, using less than 1 percent by weight of surfactant, based on the total weight of the composition.

In fact, one skilled in the art, at the time the invention was made, would have expected the presence of salts in the composition to affect the viscosity response of the gellant, and thus destabilize the gel, in the absence of a significant level of surfactants. See, for example, U.S. Patent No. 6,197,318, issued March 6, 2001, at column 11, line 65-column 14, line 17. As disclosed in the patent, carboxyvinyl polymers, such as Carbopols (used as gellants in the WO'559 reference) are known to demonstrate poor salt tolerance when incorporated into external use compositions containing salts, such that the compositions containing the polymers have poor stability (column 11, line 65 - column 12, line 3). It is also disclosed in the patent that, although surfactants had traditionally been used in cosmetic emulsion compositions to provide stability, it was becoming increasingly desirable to limit the amount of surfactants due to safety and environmental considerations (column 13, lines 58-67). Additionally, it is discussed in the patent (column 14, lines 1-17) that although carboxyvinyl polymers were considered for use as surfactant replacements, the poor salt tolerance of the polymers required the presence of a further component, e.g., xyloglucan, in the case of the patent, to impart stability to the composition. It is considered surprising and unexpected; that is, entirely unpredictable, in view of the teachings in the references, and the knowledge of those skilled in the art at the time of the present invention, that the polymeric sulfonic acid gellant would be unaffected by the presence

of salts in the composition, such that a stable, smooth, non-pilling gel would result without the need for significant levels of surfactants in the composition.

The Appellants acknowledge that the WO'559 reference discloses a composition containing a biliquid foam dispersed in an aqueous phase. However, the only teaching in the reference of such compositions having a pH less than 7 is found in the first three examples. While Example 1 of the reference contains less than 1% of surfactants – polyoxyethylene lauryl ether and lauryl betaine, and the pH of the aqueous phase is 6.5, the low pH formulation not only lacks the presence of a polymeric sulfonic acid gellant, but also fails to include a further essential feature of the claimed invention: an aqueous phase comprising from about 1 to about 10% salt.

As discussed on pages 1 and 2 of the present specification, the problem in the prior art addressed by the present invention is how to formulate a stable, water-based gel-type composition, while achieving the maximum efficacy of incorporated actives, particularly oil-soluble actives, and maintaining an aesthetically pleasing, i.e. clear and non-pilling, appearance and an aesthetically appealing, i.e., creamy, texture. The problem is compounded since many actives can disrupt gel structure, leading to an unstable product with an unacceptable feel on the skin, even moreso when the actives comprise acids, present as electrolytes. Therefore, even were the gellant in the Example 1 formulation of the WO'559 reference replaced by the gellant taught by the Clariant reference, the resulting formulation would not be the same as the Appellants' compositions, since the resulting formulation would lack the presence of substantial amounts of electrolytes/salts.

Examples 2 and 3 of the reference are directed to conditioning shampoos, the low pH formulations each also including 3% NaCl. However, even were the gellant of these formulations replaced by the gellant taught by the Clariant reference, these formulations also would not meet the limitations of the present claims, which require less than 1% surfactant. Each of the formulations of reference Examples 2 and 3 contains over 20 weight percent surfactants, including ammonium lauryl sulphate, ammonium lauryl ether sulphate, cocamidopropyl betaine, coconut diethanolamide and cetostearyl alcohol. The amount of the aqueous ammonium lauryl sulphate alone in each of the Example 2 and 3 formulations is 13.5% (33% aqueous solution x 41wt. % of the total composition). As disclosed in the reference at page 5, line 27–page 6, line 10, shampoos and shower gels generally contain 4-18% by weight of a primary surfactant and 2-15% by weight of a coactive surfactant. It is disclosed in particular on page 5, lines 7-10 that, "It is clear from the above description that by the nature of the conventional formulations this kind of dispersion contains a higher proportion of surfactant than those previously described as features

of the invention.” In fact, it is well known that, particularly in shampoos, surfactants are the primary cleansing agent and that surfactants are selected based on proper detergency without degreasing (cleaning without removing too much oil from the hair), ability to form delicate and rich bubbling, easy rinsing, good finish after washing hair, minimal skin/eye irritation, no damage to hair, low toxicity and good biodegradability. Generally, the higher alcohol type-anion surfactant provides the proper detergency and forms rich bubbles, and a non-ionic surfactant is added as coadjuvant. Additionally, the proper balance of surfactants provides a shampoo with a slightly acidic pH of about 5.5 - 6.5, since a basic environment weakens the hair by breaking the disulfide bonds in hair keratin. Citric acid is typically used to provide the desired pH. The cuticle of the hair, which is exposed after the sebum is stripped away, is covered with overlapping scales that are smoothed and soothed in a properly acidic environment. Aggravated scales don’t overlap nicely, and they make hair look dull and feel rough. They can also snag other raised scales on neighboring shafts, resulting in snarls. Therefore, Examples 2 and 3, the only disclosure of low pH, salt-containing compositions in the WO’559 reference, fail to disclose or suggest the Appellants’ invention. The Appellants’ claims require a composition comprising an oil-containing biliquid foam dispersed in a salt-containing aqueous phase, the aqueous phase comprising 0.01–10% of a polymeric sulfonic acid gellant and having a pH of less than 7, the salt contained in the aqueous phase being present in the composition in an amount of 1 - 10%, and the composition comprising less than 1% surfactant. As discussed above, one of ordinary skill in the art, reading the disclosure in the WO’559 reference, at page 6, lines 7-10, together with Examples 2 and 3, would simply not have been led to reduce the total amount of surfactants in the low pH shampoo formulations of examples 2 and 3 in the WO’559 reference. Given the state of the art at the time the present invention was made (see U.S. Patent 6,197,318, discussed herein), there would have been no reasonable expectation that a polymeric sulfonic acid gellant, such as that described in the Clariant reference, would have successfully gelled low pH compositions containing a significant level of salt, such as the shampoo formulations in Examples 2 and 3 of the WO’559 reference, in the absence of substantial amounts of surfactants to stabilize the formulation. The difficulty in gelling a low pH aqueous composition containing a significant level of salt is not at all contemplated by the reference. The only teachings one of ordinary skill in the art could have derived from the WO’559 reference concerning gelling low pH formulations are that, in the absence of salts, very little surfactant will stabilize the composition, while in the presence of salts, a significant amount of surfactant is required to stabilize the composition.

The Examiner’s position, in the Advisory Action of May 8, 2008, is that the Appellants’ arguments are not persuasive because Examples 1-3 in WO’559 represent only specific

embodiments of the biliquid-containing aqueous compositions, and the reference generally discloses that the formulations described therein also may contain salts, or may contain surfactants in the amount of less than 1% to stabilize the formulations. That the WO'559 contemplates compositions which may contain salts in an amount in the range called for by the Appellants' claims, or which may contain very low levels of surfactant is not sufficient to place the Appellants' invention into the possession of one of ordinary skill in the art. The mere fact that references can be combined or modified does not render the resultant combination obvious unless the results would have been predictable to one of ordinary skill in the art. *KSR International Co. v. Teleflex Inc.*, 82 USPQ 2d 1385, 1396 (US 2007). Nowhere in the cited reference is there described a biliquid foam dispersed in a gelled aqueous medium where the gellant used is polymeric sulfonic acid; the pH of the composition is less than 7; the composition contains about 1-10% salts; and the composition is stabilized with less than about 1% surfactant. In the present case, the use of the polymeric sulfonic gellant results in advantages, as discussed herein, which are entirely unpredictable from the cited reference.

The Examiner further asserts, in the Advisory Action of May 8, 2008, that the disclosure in the Clariant brochure of Aristoflex® AVC as a known gellant which may be used under low pH conditions supports the motivation to use the gellant in the composition of the WO'559 reference. Nevertheless, the Clariant reference includes four examples of OW emulsion compositions containing the Aristoflex® AVC gellant, and 2.0 – 4.0 percent surfactants, by total weight of the composition. There is no disclosure in the Clariant reference of a low pH, salt-containing gelled aqueous composition which is stabilized with less than 1% surfactant. Thus, not only does this reference too not contemplate the difficulty in the prior art of gelling a low pH aqueous composition containing a significant amount of salt, the reference does not provide any teaching to compensate for the defects of the disclosure of the WO'559 reference, as it relates to the presently claimed formulations, since it too fails to disclose or suggest a composition comprising an oil-containing biliquid foam dispersed in a salt-containing aqueous phase, the aqueous phase comprising 0.01–10% of a polymeric sulfonic acid gellant and having a pH of less than 7, the salt contained in the aqueous phase being present in the composition in an amount of 1 - 10%, and the composition comprising less than 1% surfactant.

The combined teachings of the references fail to place the claimed invention in the possession of one of ordinary skill in the art, since, while the skilled person might have been led to try the Aristoflex® described in the Clariant reference as the gellant in the dispersions in the WO'559 reference, the person of ordinary skill in the art would not have been led to also vary the concentrations of salt and surfactant so as to arrive at the Applicants' invention. It could not

have been predicted, by those skilled in the art, that the substitution of the polymeric sulfonic acid gellant, as taught by Clariant, for the conventional gellants in a low pH formulation, including a significant level of electrolytes, such as Examples 2 or 3 of the WO'559 reference, would have permitted a reduction in the total amount of surfactant used to stabilize the formulation to less than 1%. As noted in the present specification at page 3, line 26–page 4, line 6, the gellants recommended for use in the WO'559 reference perform adequately in non-acidic formulations; however, these gellants are incapable of creating a stable dispersion when the aqueous phase to be gelled contains even low levels of electrolytes (e.g., salts of desired active ingredients) at an acidic pH. The Appellants have previously submitted two Declarations (under 37 CFR 1.132, by inventors Harrison and Matathia-Jacobs) which demonstrate that, under certain conditions, including a pH of less than 7, a salt-containing aqueous phase, and less than 1% surfactants, carbomers, as well as other gellants recommended by the WO'559 reference, for gelling a biliquid foam-containing aqueous gel composition, do not provide a homogeneous, stable, and aesthetically and commercially acceptable product. On the other hand, it is clear from the Declarations that the use of the polymeric sulfonic acid gellant does not merely result in a superior gelling effect, but in a surprising benefit, e.g., an entirely unpredictable outcome. Any efficacy of the polymeric sulfonic acid gelling agents to stabilize an oil-containing biliquid foam dispersed in a salt-containing aqueous phase having an acidic pH of less than 7, in the absence of significant quantities of surfactants, could not have been predicted by those of ordinary skill in the art from the teachings in the cited references and the knowledge of those of ordinary skill in the art at the time of the invention. The unexpected results unequivocally rebut any *prima facie* case of obviousness that may be found in combining the WO'559 and the Clariant references. ((*In re Soni*, 54 F.3d 746, 34 USPQ2d 1684 (Fed. Cir. 1995). When an applicant demonstrates substantially improved results ... and states that the results were unexpected, this should suffice to establish unexpected results in the absence of evidence to the contrary.))

CONCLUSION

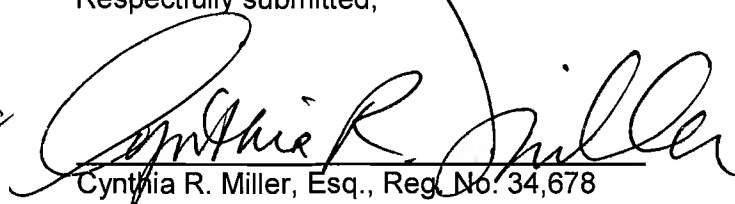
The WO'559 reference discloses low pH formulations of biliquid foam dispersed in an aqueous phase, which may be stabilized with less than 1% surfactant. The Clariant brochure discloses a polymeric sulfonic acid gellant useful in gelling a low pH aqueous phase of an emulsion. Nevertheless, nowhere in either reference is the difficulty in gelling a low pH, salt containing aqueous phase contemplated, and nowhere in either reference is there any disclosure which would have suggested to one of ordinary skill in the art that the polymeric sulfonic acid gelling agent would be efficacious in stabilizing an oil-containing biliquid foam dispersed in a salt-containing aqueous phase having an acidic pH of less than 7, in the absence of significant quantities of surfactants. Such an unexpected and surprising benefit could not have been predicted by those of ordinary skill in the art from the teachings in the cited references and their knowledge at the time of the invention. The unexpected results unequivocally rebut any *prima facie* case of obviousness that may be found in combining the WO'559 and the Clariant references.

In light of the arguments presented herein, the obviousness rejections of claims 1-10; 12-16, 18; and 19-21, based on the WO'559 reference in view of the Clariant brochure, should be reversed as they are unfounded. Accordingly, the Appellants respectfully request that the Honorable Board reverse the decision of the Examiner finally rejecting the pending claims and declare that all pending claims in this application are allowable.

Respectfully submitted,

Date:

July 31, 2008


Cynthia R. Miller, Esq., Reg. No. 34,678
Estee Lauder Companies
155 Pinelawn Road, Suite 345 South
Melville, N.Y. 11747
Tel. (631) 414-6068

CLAIMS APPENDIX

1. A cosmetic or pharmaceutical composition comprising an oil-containing biliquid foam dispersed in a salt-containing aqueous phase the aqueous phase comprising a polymeric sulfonic acid gellant and having a pH of less than 7, the salt contained in the aqueous phase being present in the composition in an amount in the range of from about 1 to about 10 percent, the gellant being present in the composition in an amount in the range of from about 0.01 to about 10 percent, and the composition comprising less than about 1 percent surfactant, wherein said weights are by weight of the total composition.
2. The composition of claim 1 in which the polymeric sulfonic acid is ammonium poly(acryldimethyltauramide-co-vinylformamide).
3. The composition of claim 1 in which the oil-containing biliquid foam comprises at least one oil, water and the at least one surfactant.
4. The composition of claim 1 in which the salt is derived from an alpha- or beta-hydroxy acid.
5. The composition of claim 4 in which the acid is selected from the group consisting of lactic acid, malic acid, glycolic acid, citric acid, tartaric acid, and salicylic acid.
6. The composition of claim 2 in which the gellant is present in an amount of about 1 to about 10% by weight of the total composition.
7. The composition of claim 2 in which the gellant is present in an amount of about 1 to about 5% by weight of the total composition.
8. The composition of claim 1 in which the biliquid foam contains a silicone oil.
9. The composition of claim 1 in which the oil portion of the biliquid foam is present in an amount of from about 50 to about 90% by weight of the foam.

10. The composition of claim 1 in which the biliquid foam comprises from about 30% to about 70% by weight of the total composition.

12. A cosmetic or pharmaceutical composition comprising a silicone-oil containing biliquid foam dispersed in a salt-containing aqueous phase, the aqueous phase having a pH of less than 7 and comprising an ammonium poly(acryldimethyltauramide-co-vinylformamide) gellant; the salt contained in the aqueous phase being present in the composition in an amount in the range of from about 1 to about 10 percent, the gellant being present in the composition in an amount in the range of from about 0.01 to about 10 percent, and the composition comprising less than about 1 percent surfactant, wherein said weights are by weight of the total composition.

13. The composition of claim 12 in which the biliquid foam comprises at least one silicone oil, water, and the at least one surfactant.

14. The composition of claim 12 in which the biliquid foam is present in an amount of from about 30 to about 70% by weight of the total composition.

15. The composition of claim 12 in which the oil phase of the foam comprises from about 50 to about 90% by weight of the foam.

16. The composition of claim 12 in which the salt is derived from an alpha or beta hydroxy acid.

18. The composition of claim 12 in which the gellant is present in an amount of from about 1 to about 10% by weight of the total composition.

19. A method of thickening a composition comprising biliquid foam dispersed in a salt-containing aqueous phase having a pH less than 7 comprising gelling the aqueous phase with a polymeric sulfonic acid gellant; the salt contained in the aqueous phase being present in the composition in an amount in the range of from about 1 to about 10 percent, the gellant being present in the composition in an amount in the range of from about 0.01 to about 10 percent, and the composition comprising less than about 1 percent surfactant, wherein said weights are by weight of the total composition.

20. The method of claim 19 in which the gellant is ammonium poly(acryldimethyltauramide-co-vinylformamide).

21. The composition of claim 20 in which the gellant is present in an amount of from about 1 to about 10% by weight of the total composition.

EVIDENCE APPENDIX

1. Declaration of Michelle Matathia-Jacobs under 37 CFR §1.132, submitted with the Applicants' response of August 27, 2001, and considered and entered by the Examiner in the advisory action of September 19, 2001.
2. Declaration of James T. Harrison under 37 CFR §1.132, submitted with the Applicants' response of March 18, 2003, and considered and entered by the Examiner in the advisory action of March 31, 2003.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Zecchino et al.

Serial No.: 09/510,756

Group Art Unit: 1615

Filed: February 22, 2000

Examiner: B. Fubara

For: GELLED AQUEOUS COSMETIC COMPOSITIONS

DECLARATION UNDER 37 CFR 1.132

I, MICHELLE MATATHIA JACOBS, declare and state as follows:

1. I am one of the inventors named in the above-identified application.
2. The experiments described in the specification, and in the present declaration, were conducted by me or a coinventor, or under our direct control and supervision.
2. I understand that the Examiner in the subject application has asserted that the application contains no data comparing the claimed polymeric sulfonic acid with other water soluble gellants. In particular, I understand that the Examiner has questioned the criticality of using a polymeric sulfonic acid in gelling a composition containing a biliquid foam dispersed in an salt-containing aqueous phase, where the pH of the composition is less than 7.
3. I am familiar with biliquid foams, particularly the biliquid foams disclosed in Wheeler, WO 97/32559, and have worked with several formulations of the type described in the Wheeler document.
4. In the course of the development of the present invention, I was asked to formulate a cream product based on a lotion (i.e., water-thin) product formula that contained a biliquid foam component as well as an acid component. To create the cream product, it was necessary to find a way to thicken, or gel, the water phase in which the biliquid foam would be dispersed, to achieve a creamy texture. I began testing a series of formulations which were, in all pertinent aspects, substantially the same as the formulation in Example 1 of the present specification, the variables being the gellant and amounts thereof employed and the acid used being lactobionic acid rather than lactic acid.

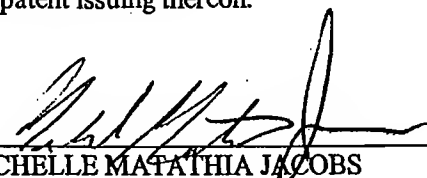
5. The following gellants (category of gellant, and amounts tested, in parentheses) were tested in the base formula: Carbopol 980 (carbomer, at 10%); Natrosol 250 HHR (hydroxyethylcellulose at 0.25%, 0.5%, 0.75% and 1%); Keltone HVCR NF(algin at 0.5%); Carbopol Ultrez(carbomer at 0.3% and 0.5%); Cellosize Polymer (hydroxyethylcellulose at 0.25%); Kelcosol (algin at 0.5%); Structure SJ (starch, at 6% and 31.24%); Aristoflex AVC(polymeric sulfonic acid, at 1% and 2%).

6. Except for the Aristoflex AVC, the polymeric sulfonic acid, none of the gellants tested produced an acceptable product. In all cases, the gellants either failed to produce adequate viscosity, or if a cream-like viscosity was achieved, the resulting product was either lumpy or pilled when rubbed out, and therefore aesthetically and commercially unacceptable.

7. Following the guidance provided in Wheeler, using polymers recommended for gelling the biliquid foam containing compositions, I was unable to achieve a satisfactorily thickened product. It was only with the use of the polymeric sulfonic acid that a cream product with acceptable aesthetics was achieved.

8. I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine, or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date: 8/17/2001

By: 
MICHELLE MATATHIA JACOBS

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of :Zecchino et al.

Serial No.: 09/995,358

Group Art Unit: 1615

Filed: November 26, 2001

Examiner: B. Fubara

For: GELLED AQUEOUS COSMETIC COMPOSITIONS

DECLARATION UNDER 37 CFR 1.132

I, JAMES T. HARRISON, declare and state as follows:

1. I am one of the inventors named in the above-identified application.
2. I understand that the Examiner has rejected claims of the application as being obvious in view of the Wheeler (WO 97/32559) reference in view of two other references. It is my understanding that the Examiner has in essence stated that, in view of the combined prior art references, it would have been obvious to substitute a polymeric sulfonic acid for the traditional water soluble gellants disclosed in Wheeler to obtain a composition of the present invention.
3. I am familiar with the Wheeler reference. It is my belief that the use of a polymeric sulfonic acid as a gellant of an electrolyte-containing aqueous phase in which an oil-containing biliquid foam is dispersed provides an unexpected advantage over the use of a more

traditional gellant, such as is recommended in Wheeler. In particular, the present inventors have found the compositions of the present invention to maintain stability under conditions that induce instability in the Wheeler compositions.

4. In order to demonstrate the superior stability of the claimed compositions over those of the prior art, I conducted a comparison between a first formula of the type disclosed in Wheeler, namely the toner in Example 5, in which a carbomer type of thickener is used to gel the aqueous phase, and a second formula, differing from the first only in the use of a polymeric sulfonic acid as the gellant, as required by the present claims. The formulas for each composition are attached hereto as Exhibit A. The Wheeler formula will be referred to herein as Formula A, and the formula of the present invention as Formula B.

In each formula, an equivalent amount of gellant (0.08% solids) was used. In addition, to each was added an equivalent amount of NaCl (0.02%) was used to provide the presence of electrolytes in the formula. The final pH of the formulas ranged from about 4.9 (Formula B) to about 5.5 (Formula A), the slight difference being attributable to the different chemical nature of the gellants. However, in each case, pH was below 7, as required by the present claims.

5. Each formula was subjected to a freeze-thaw procedure, which is a standard industry test used to determine the relative stability of a cosmetic formula. In brief, each formula is first frozen for 24 hours at -17°F and then returned to room temperature for 24 hours. This process is then repeated two more times for a total of three times. After the procedure is completed, each formula is observed for signs of instability. At the end of the procedure, Formula A was exhibiting syneresis, i.e., the gel had contracted with a concurrent release of

fluid. In contrast, Formula B retained its integrity after the three freeze-thaw cycles.

6. These results demonstrate that products prepared according to the present invention have a greater level of stability than those prepared in accordance with the teachings of the Wheeler reference. In particular, the results demonstrate that the polymeric sulfonic acids of the present invention are superior to the traditional water-soluble gellants, such as the carbomers that are recommended in Wheeler, in their ability to produce a stable gel.

7. I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine, or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

By: _____

James T. Harrison

Date: _____

3-18-03

EXHIBIT A

Note: Biliquid Foam in each formula prepared according to Example 1 of Wheeler, using the oils designated in Example 5

Formula A

| SEQUENCE | TRADE NAME/ CTF A NAME | PERCENT |
|------------------------------|--|-------------------------|
| 01 - 10 | DEIONIZED WATER PURIFIED WATER | 0.546000 |
| 02 - 10 | DOW CORNING 345 FLUID CYCLOMETHICONE | 5.400000 |
| 02 - 20 | VOLPO L3 SPECIAL C12-13 PARETH-3 | 0.054000 |
| 03 - 10 | DEIONIZED WATER PURIFIED WATER | 0.091000 |
| 04 - 10 | DOW CORNING 2-9023 FLUID DIMETHICONOL | 0.900000 |
| 04 - 20 | VOLPO L3 SPECIAL C12-13 PARETH-3 | 0.009000 |
| 05 - 10 | DEIONIZED WATER PURIFIED WATER | 83.840000 |
| 05 - 20 | GLYCERINE USP 99% (VEGETABLE) GLYCERIN | 5.000000 |
| 05 - 30 | MERGUARD 1200 METHYLDIBROMO GLUTARONITRILE/PHENOXYETHANOL | 0.100000 |
| 06 - 10 | CARBOPOL 980 (2% AQ SOLUTION) | 4.000000 |
| 06 - 20 | CAUSTIC SODA 30% WATER/SODIUM HYDROXIDE | 0.040000 |
| 07 - 10 | SODIUM CHLORIDE GRANULAR USP SODIUM CHLORIDE | 0.020000 |
| TOTAL NUMBER OF ELEMENTS: 12 | | TOTAL PERCENT: 100.0000 |

Formula B

| SEQUENCE | TRADE NAME / CTFA NAME | PERCENT |
|------------------------------|--|-------------------------|
| 01 - 10 | DEIONIZED WATER PURIFIED WATER | 0.546000 |
| 02 - 10 | DOW CORNING 345 FLUID CYCLOMETHICONE | 5.400000 |
| 02 - 20 | VOLPO L3 SPECIAL C12-13 PARETH-3 | 0.054000 |
| 03 - 10 | DEIONIZED WATER PURIFIED WATER | 0.091000 |
| 04 - 10 | DOW CORNING 2-9023 FLUID DIMETHICONOL | 0.900000 |
| 04 - 20 | VOLPO L3 SPECIAL C12-13 PARETH-3 | 0.009000 |
| 05 - 10 | DEIONIZED WATER PURIFIED WATER | 79.800000 |
| 05 - 20 | GLYCERINE USP 99% (VEGETABLE) GLYCERIN | 5.000000 |
| 05 - 30 | MERGUARD 1200 METHYLDIBROMO GLUTARONITRILE/PHENOXYETHANOL | 0.100000 |
| 06 - 10 | ARISTOFLEX AVC/ USA AMMONIUM ACRYLODIMETHYLTAURATE/VP COPOLYMER | 0.080000 |
| 06 - 20 | DEIONIZED WATER PURIFIED WATER | 8.000000 |
| 07 - 10 | SODIUM CHLORIDE GRANULAR USP SODIUM CHLORIDE | 0.020000 |
| TOTAL NUMBER OF ELEMENTS: 12 | | TOTAL PERCENT: 100.0000 |

RELATED PROCEEDINGS APPENDIX

There are no related proceedings or decisions.